

# A randomised controlled trial to compare the efficacy of three new formulations of Ready-to-Use Therapeutic Food (RUTF) in the treatment of severe acute childhood malnutrition

<b>Submission date</b> 16/12/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/07/2009	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

## Acronym

PRONUT Study

## Study objectives

In a population of severely malnourished children:

1. Low-milk/chickpea-based RUTF (Ready-to-Use Therapeutic Food) is non-inferior (one-sided equivalence hypothesis) to high-milk/peanut-based RUTF.
2. Probiotic/Prebiotic enhanced ('Synbiotic 2000 Forte') RUTF is superior to standard RUTF.

Due to a delay in the food acceptability pilot studies, the trial was simplified to test only the second hypothesis:

Probiotic/Prebiotic enhanced ('synbiotic 2000 Forte') RUTF is superior to standard RUTF.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

College of Medicine Research and Ethics Committee, Malawi (COMREC) (reference number: P03/04/236). Final approval, including amendments: 10th November 2005.

Simplification of study to test only second hypothesis approved April 2006.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Quality of life

## Participant information sheet

## Health condition(s) or problem(s) studied

Severe acute malnutrition

## Interventions

The initial plan was that after initial in-patient stabilisation with F75 milk, enrolled children would be randomised to one of four different types of RUTF:

1. (Control) Standard, high-milk/peanut based RUTF
2. Standard RUTF with added synbiotic
3. New formulation low-milk/chickpea-based RUTF
4. New formulation RUTF with added synbiotic

Due to delays in the food acceptability pilot studies, the trial was simplified prior to start, and as of beginning of enrolment in July 2006 is testing only:

1. (Control) Standard, high-milk/peanut based RUTF
2. Standard RUTF with added synbiotic

The simplified study started enrolling patients on 12th July 2006, and is expected to end in April 2007.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Nutritional cure (%)

### **Secondary outcome measures**

1. Death rate (%)
2. Rate of weight gain (g/kg/day)
3. Incidence of illness episodes (including diarrhoea)
4. Length of stay in programme (days)
5. Default rate (%)

### **Overall study start date**

27/01/2006

### **Completion date**

27/04/2007

## **Eligibility**

### **Key inclusion criteria**

All children suffering from severe acute malnutrition (World Health Organisation [WHO] criteria: less than 70% weight/height and/or oedema) admitted to Moyo Malnutrition Ward, Queen Elizabeth Hospital, Blantyre, Malawi

### **Participant type(s)**

Patient

### **Age group**

Child

**Sex**

Both

**Target number of participants**

Initially 1200, after simplification this was changed to 800. Recruitment completed.

**Key exclusion criteria**

1. Children with severe cerebral palsy or obvious dysmorphic syndrome
2. Children less than six months of age or 4 kg weight

**Date of first enrolment**

27/01/2006

**Date of final enrolment**

27/04/2007

**Locations****Countries of recruitment**

England

Malawi

United Kingdom

**Study participating centre**

**Centre for International Child Health**

London

United Kingdom

WC1N 1EH

**Sponsor information****Organisation**

Institute of Child Health, University College London (UK)

**Sponsor details**

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London

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+ 44 (0)207 2429789

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**Sponsor type**

University/education

**Website**

<http://www.ucl.ac.uk>

**ROR**

<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**

Charity

**Funder Name**

At registration, prior to 23/07/09: Valid International (UK)

**Funder Name**

Corrected on 23/07/09: the project was funded from a core grant from the Department for International Development (DFID) (UK) to Concern Worldwide (Ireland)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	11/07/2009		Yes	No